issue that several people referred to earlier: the FDA's proposal from April of a year ago. And we all, I trust, are aware of the volume of response, and the strongly felt disagreement.

But there seems to be a belief on FDA's part, held closely and deeply, that somehow disease-related claims are not appropriate for things that are foods, and dietary supplements are a sub-category of food. In fact, the definition of "food for special dietary use," which has been in the FDA regulations since the 1940s, and which includes among the defined categories "dietary supplement products" as a type of food for special dietary use, has recognized that claims of special dietary usefulness for a food may include claims about providing usefulness with respect to physical, physiological, pathological or other conditions including, but not limited to, the conditions of disease. I've more or less got that verbatim. And that's in Part 105--I guess .3, somewhere along that line, in the definitional section.

I would submit to you that there are perfectly appropriate dietary supplement uses with respect to disease, and to say that something is "disease-related," to use the conceptual dividing line that FDA often uses, is not an appropriate divider for deciding whether something ceases to be an appropriate food or not; and that there are very good

cases to be made, which will be made--and I hope they don't need to eventually be thrashed out in litigation--to the effect that disease-related claims are indeed appropriate in certain circumstances, for certain products, for things that are dietary supplements or, indeed, foods for special dietary use.

And I think that if we are to avoid that black hostility that I believe Jim Turner talked about earlier, that this is an apt time for the Agency to reflect on some fundamental instincts about what's acceptable for a food and a supplement, and a food for special dietary use, insofar as that's an appropriate umbrella term for supplements.

And I personally believe that there's a very good legal argument, as well as a good policy argument, that there's number of disease-related representations that deserve to get in--appropriately, properly--and that the Agency's instinct is so resistent to that, and its proposals are so resistent to that, its courtesy letters are so resistent to that, that we find ourselves dealing with these issues always in conflict situations. It's regrettable.

I mean, one of--you asked earlier about advisory committees, whether they're advisory committees, or however they're set up. It really will be advantageous to the industry and to the FDA, I think, if you can find ways for some of these issues, which have been dealt with in

contentious contexts to be dealt with in non-contentious contexts.

MR. LEVITT: Thank you.

Yes.

MS. LEWIS-ENG: I do have one comment that I would like to make.

I don't really have a clarification comment under DSHEA that I would like to ask, but I do have one under FDAMA. Since the agency is really looking at priorities at this time, I think that we should have a clear definition of what an "authoritative statement" is. I think there has been lots of upheaval in the industry--dietary supplement industry in terms of what exactly constitutes an authoritative statement, and the agencies such as NIH and the FDA and others who are approved under FDAMA don't seem to agree what an authoritative statement is. And I think that really should be clarified.

MR. LEVITT: Okay. Thank you. I think that counts.

[Laughter.]

Steve, do you have anything you'd like to add?

MR. ALLIS: Your question related to where we could establish or improve on definitions that you rely on?

MR. LEVITT: Yes.

MR. ALLIS: All I can really do is reiterate my

point is that looking at this from a legal perspective, or regulatory perspective, it's easy to ignore the science side of it, which is what I was trying to stress in my talk, which is that it's pretty easy to define what's good science and what's bad science most of the time. And as far as a definition goes, just, like I said in my speech a minute ago was that if it's going to be bad science for use for someone to apply to the Agency, it should still be bad science when the Agency wants to rely on it for passing regulations.

MR. LEVITT: Okay. Thank you.

Margaret.

MS. PORTER: Well, I have several questions I'll try to discipline myself and start with one that I actually asked the earlier panel.

I was pretty stimulated by this morning's second panel really urging the Agency to find ways of doing consumer research or having others do consumer research that really looked intensively at how dietary supplements are actually used; whether consumers really follow the labeled indication, follow the dosage indicates; whether they use supplements for purposes that are not advised by the manufacturers, and whatever, on the labeling and otherwise.

And I was interested in any comments that you might want to make on behalf of your clients about the appropriateness of that kind of research; the usefulness for

which it could be used. I know that in the Pearson context there is a strong suggestion that the Agency look at that in the context of disclaimers. I'm acknowledging that, but also asking some broader questions, and I'd be interested in any comments you might have.

MR. PROCHNOW: In my judgment, I think it's a very important component to the resolution of all of these issues. I mean, consumers are the ones that are to benefit from taking dietary supplements. They probably drove the enactment of DSHEA. The question always is: how do you pay for this and get it done in a reasonable period of time.

Now, although I respect what the FDA has done in the past, still it seems its efforts with respect to the ephedra rule, and structure/function rule not get too far. So I think that if there's going to be some research in this industry, again it has to somehow be--the industry has to, I think, carry the water on that issue, with input from the FDA.

I think the industry wants to do some of these things, and is looking for a mechanism of how to carry this out. I think there's got to be a partnership involved here, and I think Annette Dickinson talked about a partnership this morning. I just happen to think--I'm trying to be creative and think about our clients, or about a program that the industry can buy into to fund some of these things.

Because of this requires a lot of money. And without that happening, I don't see it being done.

But we use consumer research on trademark issues in this industry all the time, and for other things. So I think it's imperative that something like that should be done.

MR. McNAMARA: I trust the assumption is that it's not being done in all cases. I mean, there are some substantial companies--I would assume, but I don't know that I have the right to make the assumption--often the larger ones, that have, I know, spent a great deal of money on appropriate research of various kinds. I think the first focus tends to be on the substantiation of the health-related structure/function statement, but there--it's not appropriate to name brand names up here, but there's a major line of products out there now with a clinically-proven representation on the front panel. I think you'll find that people who are making those kinds of claims have done a lot of work to substantiate those, at least certain of the companies that are larger companies, that I'm familiar with are, in fact, doing that.

And--so I wouldn't reach the quick and cavalier assumption that things are not being done, or at least that it's any materially different than perhaps you find with respect to other industries that FDA regulates, where

there's a variety of performance. But you should also not judge companies that do comply by those that don't. And I think that there are many out there who feel that sometimes they've put in the work to defend what they've got, and then they're tarred by generalizations that are made about others.

One of the other factors that I really think is important here that no one has raised yet, and that I know that Dr. Yetley and Mr. Levitt have heard me raise in other contexts, has to do with insofar as you're worried about a definition, or insofar as you're--you know a product is a supplement or a drug, or insofar as you're worried about whether a claim is an appropriate claim or not; insofar as the Agency expresses an opinion, it ought to be willing to follow through on that opinion.

And one of the negative impacts right now that we are all living with, if we're honest, is that the Agency is issuing letters that express opinions that nobody pays attention to; or that the addressees have paid no attention to. I've mentioned one that I know--again, I'm not going to mention a brand name up here, but anyone out there in the industry's probably familiar. I mean, the Agency sent at least five letters expressing the view that a particular name and claim are illegal and inappropriate for a particular product that's quite successful. And it has been

increasingly successful, notwithstanding the FDA's repeated letters. And the Agency's done nothing, and the product is just booming in the marketplace.

Now, believe me, when other companies come and consult with you about, "Well, can we make the following claim or not," and you say, "Well, you know the agency issued a letter about that point last year." And they say, "Tell me about something other than an FDA letter. I know what happened to the letter that FDA wrote that other company. They didn't do anything to follow through on it. The people that withheld from meeting the competition lost lots of money. And I have no confidence in FDA paper."

And whatever structure you come up with--earlier commenters this morning, I noticed, were talking about enforcement. I'm not up here to ask you to go out and have enforcement actions. I'm here to defend companies. But I believe that the wrong way to have the railroad run is for the Agency to express views that it does not follow through upon. You're wasting your money if you're sending that kind of a letter. You're not only getting no bang for the buck out of it, but you're undermining the respect for the agency in other contexts.

And a fundamental question should be going through the head of the Agency, whenever it expresses an opinion in writing, and that is: do we mean it enough that we mean it?

Or are we just putting it out there, and if people ignore it, we'll do nothing. And--enough to say on that.

Others?

MS. LEWIS-ENG: Whenever it comes to scientific substantiation, the question of money always arises. And I represent a number of clients who wouldn't be afraid or unwilling to spend a substantial amount of money to submit scientific substantiation to the Agency if they had faith that the Agency would take an objective view of the scientific substantiation.

In the past, when I sort of encouraged this type of clinical trials and whatnot, to take place, the most--the response I received most often is that, "I'm not certain that the FDA is going to take this scientific evidence that I produced seriously, based on its past actions that the Agency has taken."

So I would submit to the Agency that perhaps until the industry has more faith in the Agency, in terms of being objective and not having biases, if you will, that perhaps the Agency could team up with universities, or private contractors, if you will, to come up with some scientific information that everyone could pull from, and they get a grasp of what the Agency is actually looking for, and what will work with the Agency. And they might be willing to spend their own dollars on the scientific substantiation.

MR. LEVITT: Thank you.

Did you want to say something? Please.

MR. ALLIS: Like what I've stated before is that the companies do want--for the most part, do want to do the science. The clients that I represent with Ms. Lewis-Eng, they have an interest in having the science and putting the investment into the product. Of course, there's something you should keep in mind, which is that there's a risk not only that the other guy in the market won't have to be meeting the same burden, also, as I've seen in dealing with science and submission to the Agency, there's very little guidance sometimes, or access to people who will be reviewing the science, to find out whether a little flaw is going to be a fatal flaw later on when you come to the end of your study. That could be a huge expense, especially for the smaller companies that predominantly are found in this industry.

Another thing I would want to bring up is that the health-claims petitions that we filed recently--adopting health claims such as that might alleviate the need for some of the dietary supplement claims that are being generated by individual manufacturers, if they could rely, or fall back on a health-claims petition--or, I'm sorry, an approved health-claims petition. Maybe that statement might forego the need to come up with, maybe, some more extravagant

claims or objectionable claims.

MR. LEVITT: Thank you.

Before we move on to Dr. Yetley, let me note that Mr. Hubbard needed to leave. And I'm sure, Margaret, Bill would want to have yielded his time to you. And so, when we finish, if you'd like to have another couple of questions, I'm sure this group is eager to answer them.

Beth.

DR. YETLEY: Some of the previous panels had urged the FDA to take stronger action relative to safety and substantiation of claims.

How would you recommend that the FDA deal with the recommendations that hey were making to us?

MS. LEWIS-ENG: Well, I wasn't here this morning. But, of course, safety is of the utmost concern. As a consumer myself, I wouldn't advise the Agency to just put products on the market because there was some inclusive scientific evidence that wasn't really--didn't substantiate the claim at all.

What I'm looking for is that very rarely in the scientific is there a total agreement, and I'm just looking for some balance that the Agency can put on the health claims and substantiation requirement so that the small actors, as well as the large actors in the industry, can compete effectively in the market--with safety, of course,

being the number one concern.

MR. PROCHNOW: In my judgment, the biggest thing that you could do for safety right now, I think, is to either adopt the GMPs that have been proposed by the industry in a guidance document, or issue a regulation for them. It will send a signal to the industry that this GMP process, and other processes, can have an end to them, and that the FDA can bring to finality certain things.

It's important, not only for the substance of them, but for the fact that they are actually issued, in the form of a guidance document or regulation. Because right now, whether it's in the context of just manufacturers and distributors wanting to be able to have safe products, but people will conform to a--whether it's a quasi-regulatory document like a guidance document or a regulation--but I believe there's got to be some finality to the GMP process, and that's the single biggest thing at the present time.

The second thing, I think, is selective--maybe sending out more warning letters and then, as Mr. McNamara suggested, taking some action with respect to some of the warning letters, because that makes a difference and an impact in the industry as well.

MR. LEVITT: Okay.

DR. BOWEN: I'm tempted to yield my question, but I guess I'm very curious, so I'm going to ask it.

Mr. Prochnow, you mentioned that you thought that FDA could get a lot of mileage out of holding meetings across the country in areas where consumers use dietary supplements pretty extensively. If that were possible, how would you envision those meetings to happen? The forum of those meetings?

MR. PROCHNOW: How do I envision them to happen in what? I'm sorry.

DR. BOWEN: Sort of the format, the forum of these--

MR. PROCHNOW: Yes. I think basically what it would be is this--is that you would send out a notice--let's just pick Colorado Springs--that there will be a meeting in Colorado Springs, and the people that will be there will be the District Director of Colorado and somebody--let's say Bob Moore--from the Washington, D.C. office. There will be a topic presented--let's say it's quality control and good manufacturing practices in the dietary supplement industry. I think there should be a short, like, overview, and maybe that topic divided into five segments. And then the meeting should be split up with, let's say, 10 people--let's say you have 40 people there--10 people in a session that considers one of the issues, reports back and makes recommendations to the group as a whole.

I think that process, you know, can take a half

day or take a day, but it worked really effectively in the meetings I went with the medical device community, and it's been just--the people I've talked to have come away feeling that they finally had the FDA listening to things. And it's just so often that there's so little chance for a mass of people to be participating in meetings like this that you'll really find out what the multi-level marketing distributor sees as the problems it confronts, or the contract manufacturer says "Here's where I really need some help," or where we could use some more working with or regulation with the FDA.

It's that kind of format that I think would be very effective.

MR. LEVITT: Thank you.

I'll give the phone back to Margaret.

MS. PORTER: This is--actually, Dr. Bowen actually asked one of my next questions. So let me just do a little bit of follow up, because I think that your comments, when you focused on sort of taking the Agency to the--going to the people and really engaging in a grass-roots way, I think the Agency also found the Denver meetings with the medical device industry quite productive, in terms of really having a way of listening to concerns and responding to them.

There are several different kinds of people that I think the Agency's interested in trying to reach out to at a

grass-roots level. Certainly one kind of stakeholder is the industry itself, and you suggested, I think, the forum under which the Agency might do that.

Do you have some suggestions for reaching consumers directly? We've obviously heard from a number of national or regional consumer organizations today, but I'd be interested if you've got some suggestions for grass-roots consumer outreach as well.

MR. PROCHNOW: I'll let others speak to it. But one thing I do want to say is I think the gentleman who represented AARP had a really good suggestion. I'm now an AARP member, for all of you that were wondering.

[Laughter.]

But their magazines--I mean, I read Modern Maturity. I'm 55 years old now and all of that, and it's the people who are in that age category--this is important things, and they respond to it. And you're talking about a huge segment of the American population. So I think the use of some mass media opportunities like that is the best way that I can think of. But others probably have other ideas about that.

MR. McNAMARA: It strikes me there are lots of interesting and important segments of consumers. A significant segment of dietary supplement users, it appears to me, based on things that have just happened to come up in

our practice of the law, include younger people in college and high school. There's a group of people who are highly interested in issues relating to diet and health and in supplements, and in alternatives, and I assume there are ways to reach college-age people as well. And one--again, we're lawyers, not marketing folks, but one certainly can get advice about reaching the various segments.

But it seems to me the important issue is to try and reach a lot of them. Sitting here as another--I hate to say how many years'--member of the AARP, but those--my children never read those magazines. Let's put it that way.

MR. LEVITT: Okay. Thank you very much.

Before we let you walk back down, we get the one final question: looking ahead a year from now, if FDA could do one thing it would be?

MR. ALLIS: Umm--

MR. LEVITT: One thing.

MR. ALLIS: One thing.

[Laughter.]

MR. ALLIS: Better access through guidance and interaction with your review staff so we can hit these targets that seem to be moving targets some times; the definitions and such.

MR. LEVITT: Okay.

Steve McNamara.

MR. McNAMARA: Well, I'm here for a particular client, so focusing on that particular's interest I'd like to see FDA withdraw the pending proposal on ephedra; have informal meetings that could then be held with the ephedra dietary supplement industry, focusing upon things that FDA may want, including long-term follow-up and issues that like, and have a guideline, or at least an indefinite interim guideline issued about the Agency's views about labeling composition and what a responsible company should be doing, including--insofar as you feel that's important--follow-up monitoring and reporting to the agency about events.

MR. LEVITT: Okay. Thank you.

Jim.

MR. PROCHNOW: I think I'm going to be able to do one--and-a-half here, because I agree with everything that Steve had to say about the ephedra rule: guidance document only.

Beyond that, I think that, seriously, all of the people here have raised this issue about maybe not more regulation but the need for the FDA to be actively involved in the process with the industry. And so therefore, at the end of this year I would hope that we have completed a round of intimate industry meetings in a lot of different districts throughout the United States, so we're in a better

position to move forward with a master strategy plan after next year.

MR. LEVITT: Okay. Thank you.

Claudia.

MS. LEWIS-ENG: And to be totally predictable--

[Laughter.]

--I would like to say I would like to see a faithful implementation by the Agency of Pearson v. Shalala. And I also would like to say that I want to rally behind Jim and Steve's request that the FDA withdraw the proposal on ephedra.

MR. LEVITT: Okay. I thank this panel very much.

As you're getting ready to get up and walk back down, there are two additional people that have asked to speak. I'd ask them to come up together, and we'll have a mini-panel here.

One is Anne Fonfa, and one is Mary Silverman. And then that will conclude our day.

Thank you very much, the four of you. And thank you for traveling--and the many other people that traveled, too.

[Pause.]

ADDITIONAL COMMENTERS

MS. FONFA: I'm just going to start.

MR. LEVITT: Thank you. If you'll just let the

gentleman behind you sit down. And again, while you're up here, we'll give you the same five minutes everybody else had--

MS. FONFA: Thank you.

MR. LEVITT: --and we've got the timer right down here in the front way. If you can identify who you are, and where you're from, and who you're representing. Thank you.

MS. FONFA: My name is Anne Fonfa, and I'm a cancer patient. I represent a group called the Annie Appleseed Project, and what we do is speak and for cancer patients who are using alternative and complementary therapies which, as you probably know, is a majority of cancer patients. I also speak to health professionals and other people about this issue.

So--patients are using complementary therapies and alternatives, which include dietary supplements and every single thing we heard mentioned here today. I echo the safety concerns of everyone else, but I have to say, for cancer patients, proof of efficacy has become the critical thing. People are doing things right now. They're not waiting for safety, and they're certainly apparently not waiting for efficacy. So, from my perspective we can solve two birds with one stone if we focus on efficacy, I think we'll find that that will resolve the safety questions pretty clearly.

Standards for drug development that we're currently using for cancer have been toxicity, terrible effects that are called "side effects" but aren't. So we're not as concerned as others might be about the safety in the same way. We don't mean it in the same way that everyone else does.

I also agree with many of the speakers that research exists and can be looked at, and I think it needs to be brought together in a way that will make it clear to cancer patients, and others, what it is that we can use appropriately.

I don't think we should limit anything to a single element. That's been a problem in both drug development and with supplements. We know that people use things in combination, and that needs to be studied directly.

We need to send a message to pharmaceutical companies that supplements can be used with their products, and that they need to be concerned about their--the dangers of their products. I don't think it's specifically the herbs and other things that are so dangerous, but the way they interact with pharmaceuticals. And I think if garlic is a blood thinner, that's not necessarily bad. It may indicate that we could consider use of garlic as a way to reduce our use of pharmaceuticals, because every pharmaceutical product as unwanted effects.

We want health care professionals to be involved. No one was here today. That's a concern of mine. I think they should be part of this process.

The final thing is I think--I wrote something here that I can't even interpret. Oh, yes--patients start a regiment of supplements, and then they become scared because they are looking at the statement that says it hasn't been evaluated by FDA. And that's a concern, because they start something and they stop it. They may desperately need something. They may have been already finished with conventional treatment, which is the way most people use alternative or complementary therapies; or they're looking for them to reduce side effects. And since they're not sure how it works, its efficacy, they lose faith in it, and they stop at a point at which they might be gaining something from it. Because we're used to pharmaceuticals, we want an instant reaction, and we know that herbals and dietary supplement may take time--at least I know that, and you all know that. But many of the cancer patients are without direct information.

So I truly think that going toward efficacy immediately, and having statements of efficacy would be extremely useful to our population. We're doing it now. Our lives are at stake. Our time is limited and our money's limited.

Thank you.

MR. LEVITT: Thank you.

Please--you may sit right there if you like.

MR. SILVERMAN: Okay. Thank you.

My name is Maury Silverman, from Silver Spring, Maryland, and I wanted to share some personal impressions.

Several people here asked your panel about completing the ephedra regulation question. And I have some impressions and thoughts I'd like to share with you, and ask your comments.

I've watched that issue through the years. I was personally somebody who worked for passage of the DSHEA law. I think it's a good law, and a good structure; and that industry and consumers and the FDA need to join ranks and work effectively and objectively to implement it and get it down to the details beyond what might be in the actual language that went through late that night at the end of that session.

I wonder if the ephedra issue is kind of a bad red herring for all of us ; all people concerned. I remember attending the two-day Food Advisory Subcommittee meeting on ephedra--it's, oh, many years ago now. And I remember well one of your best experts at the table was Varro Tyler. And he flat-out stated on the second day, "Regulate the chemical ephedrine as a drug, as it is. Regulate the botanical

ephedra alkaloids under DSHEA." And he gave labeling recommendations; label contraindications, label a maximum daily dose and per serving dose, that's objective for the benefits of ephedra.

I want to ask you two questions. I remember seeing the effects literature that was brought to that meeting, and it was clearly all effects of chemical ephedrine. And I want to ask a basic question before you decide on a final rule, or whether to accept it, toss it out, revise it, just go back to a guidance procedure--whatever.

Has FDA distinguished where the serious side effects came from? Chemical ephedrine, or botanical ephedra--also known as mah-wong; it's also known as Mormon's tea, for a good reason.

I think that's an important question to be answered, and it might clear up what some of the confusion has been, because Varro Tyler's remarks that day several years ago echo in my mind with this.

I'd also like to ask if FDA has ever determined if dietary supplements have been spiked with chemical ephedrine, and is that a possibility where some of what are called the "serious side effects" are coming from?

I also attended the Government Reform and Oversight Committee Hearing a few Thursdays ago, and a lot

of that testimony was illuminating. There was a gentleman who gave a very good historical and scientific narrative about the thermogenesis properties of ephedra. And I think that's why one of the common names for ephedra, or the botanical source is Mormon tea. It's what helped those people go west in the middle of a winter and predominantly make it there.

And I think these are important questions to be asked and answered. And like one of the previous people that were up here at this table said, please don't let the bad actors throw the good people and well-meaning people out. Please don't throw the baby out with the bath water.

One example was the testimony the other Thursday that the proposed dosages of ephedra are lower than the effective doses for thermogenesis in weight loss. And, as you know, there have been a lot of problems with some of the pharmaceutical drugs that are put in the marketplace for weight loss problems. And I think this should be done objectively and in a reasoned manner.

Some of it kind of reminds me of all the brouhaha over tryptophan which, my understanding was a problem with a Japanese manufacturer, Shawa Denka, that they took some of the activated charcoal steps out of their process and their might have been a bioengineered organism involved there was a problem with. And there was a later Mayo clinic study

that identified a contaminant. And that the lots of the those contaminated batches correlated with where the incidence of the eosinea myalgia syndrome came up--explained a lot. I heard testimony that there was virtually none of these cases in Canada, because none of those lots reached Canadian markets. And I feel sad that if issues like that are used by the people who would like to gut the DSHEA law, when we really need to implement it right.

An example, I think, would be the good manufacturing processes provisions in DSHEA could have solved the tryptophan problem before it really became a problem with eosinea myalgia syndrome. And I think these are some things that need to be thought about, taken to heart, and part of the learning process in developing this law, and implementing it properly for the public safety and in all people's interest. I think that's in all our interests, and that we should do this in a calm, reasoned manner, and look at the history of this, and do it right.

Thank you.

MR. LEVITT: Thank you very much for that presentation.

I'm not sure if you were here in the morning when we began, but one of the things I tried to explain is, today is really for us to kind of take in information and to listen, and to elicit more, and not get into a back and

forth. You know, I presume, from everything you've said that we did issue a proposed rule on ephedra a couple of years ago that did have a lot of information in there: what the agency based in on. We're now looking at all of that in trying to make the determination where to go. But, beyond that, we really--this is not the forum--

MR. SILVERMAN: No. All we realize--is we ask you to take all these comments home with you--

MR. LEVITT: Right.

MR. SILVERMAN: --and take them to heart. Thank you.

MR. LEVITT: Okay. Thank you very much. Let me thank both of you.

[Pause.]

That concludes our meeting today. We started a few minutes late, but we've finished a few minutes early. That's because, I think, number one, people came very prepared; people were very gracious and adhered to the rules of procedure that were laid out.

Let me again thank everybody who came today; people who presented. We will be taking all this information in, together with written comments at a meeting we're having on the West Coast in July, and really trying to develop--as I said at the beginning--an overall framework. Clearly our goal is to implement DSHEA in a responsible way

and to get consumers, as one of the speakers reinforced, access to products that are safe and properly labeled.

Let me thank everybody for their attention. Thank the panelists. And that will bring this meeting to a close.

[Whereupon, at 4:42 p.m., the meeting was adjourned.]

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CERTIFICATE

I, **THOMAS C. BITSKO,** the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

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